

## **REMARKS**

Claims 1-7, 9-12, and 14-20 are pending in the application with new claims 15-20 added herein.

Claims 1-7, 9-11 and 14 stand rejected under 35 U.S.C. 103(a) as being unpatentable by Silvestrini (EP 0 331 345 A2) in view of Gabbay (US Pat. No. 6,869,444). Applicant requests reconsideration.

Claim 1 sets forth a prosthetic valve that includes, among other features, at least one flap made of a flexible openwork structure of a medically acceptable metal, wherein the flexible openwork structure is selected from the group consisting of: knitted wire and chain mail. Pages 2-3 of the Office Action allege that Silvestrini discloses every limitation of claim 1 except for the openwork structure being knitted wire and relies on Gabbay to remedy the deficiency. Applicant traverses. The Office Action does not appear to allege disclosure of the openwork structure alternatively being chain mail.

Applicants refer the Office to the specification for interpretation of the term "knitted wire." Specifically, page 3, lines 15-23 refer to Figures 7a-d and state that the openwork structure may be made from wire using a knitting type of process. Alternatively, a weaving type of process may be used. Knitted wire is shown in Figure 7a while woven wire is shown in Figure 7b. Woven flaps are described as providing a relatively stiff structure while knitted flaps are more flexible.

Consequently, the present specification expressly distinguishes knitted wire from woven wire, both with respect to appearance as well as stiffness.

Figure 7a shows the intermeshing loops characteristic of a knitted material while Figure 7b contrasts such loops with the warp and weft threads running at right angles to each other characteristic of a woven material.

Relying on Webster's Revised Unabridged Dictionary available from Dictionary.com, page 3 of the Office Action refers to "knit" as "to form a fabric by interlacing yarn or thread; to weave by making knots or loops." The same reference relied on by the Office further refers to "knit" as "to form, as a textile fabric, by the interlacing of yarn or thread in a series of connected loops, by means of needles, either by hand or by machinery; as, to knit stockings." Thus, Webster's refers to "knit" in one generic sense as forming fabric by interlacing yarn or thread. However, it is apparent from the present specification that "knitted wire" in claim 1 refers to a more narrow sense of material including the intermeshing loops of Figure 7a and possessing a flexibility greater than woven material of the type shown in Figure 7b. "Knitted wire" in claim 1 thus corresponds with the more narrow definition for "knit" in Webster's.

Applicant further refers the Office to the definitions provided in the Larousse Technical Dictionary cited in the Information Disclosure Statement filed herewith. Larousse defines "knitting" as "the process of making a fabric from yarn by the formation of intermeshing loops" and defines "weaving" as "the interlacing of warp and weft threads running at right angles to each other to form a fabric." Notably, it is relevant to consider that in a weave there are two sets of threads (i.e. warp and weft), which extend in different directions

whereas, in a knit, thread is interlaced with itself. The present specification is consistent with the definitions presented in Larousse.

Page 3 of the Office Action alleges that Gabbay teaches a cardiac prosthesis constructed from knitted wire. However, review of the relied upon text of Gabbay fails to reveal disclosure or suggestion of “knitted wire,” as set forth in claim 1. Instead, column 11, line 1 merely states that frame 400 may be formed of a wire or filament configured as a “mesh or weave.” Column 13, lines 61-67 and column 14, lines 61-66 similarly refer to a wire mesh or weave. Gabbay does not otherwise contain any teaching that those of ordinary skill would consider to disclose “knitted wire,” as set forth in claim 1. None of the structures described in Gabbay include the loops characteristic of a knitted material, as discussed above. Instead, all of the structures described in Gabbay include the thread orientations characteristic of a woven material, as discussed above. At least for such reasons, the cited combination fails to disclose every limitation of claim 1.

Applicant also asserts that no motivation exists to modify the teachings of Gabbay to use knitted wire instead of the mesh or weave described therein. Page 3 of the Office Action alleges that such a modification finds motivation in order to provide a prosthesis with the desired resiliency. Gabbay (as in columns 1-2) relates to an implantable cardiac prosthesis and in particular to a prosthesis that can be implanted at the annulus of a heart valve to help improve valve operation, i.e. to help repair damaged or degenerated heart valves. The apparatus is intended to form a firm support. Column 2, line 39-41 of Gabbay states “the buttress provides a surface

against which one or more leaflets of the patients heart valve may move into and out of engagement.” The buttress of Gabbay is described as resilient in the sense that it can flex and be manipulated to a reduced cross-sectional condition to facilitate insertion, e.g. with an implantation device, such as a catheter. After insertion, the buttress is not intended to flex. Consequently, the buttress is not flexible in the sense that a heart valve flap is flexible.

The Office Action refers specifically to column 10, line 63 to column 11, line 10 wherein Gabbay describes Figure 13 and states that the support frame 400 can be deformable between reduced and expanded cross-sectional conditions (this is to assist with insertion). Frame 400 is stated to be formed of wire or filament configured as a mesh or weave. The mesh may be a metal, alloy or other suitable material which is stated to endeavor to maintain its configuration and to help anchor the prosthesis at a desired position when implanted. The examples given in column 11, line 10 onwards are shape memory alloy metal.

Column 11, line 57 to column 12, line 5 of Gabbay refers to Figure 14 and describes a frame 430 which includes a base and frame supporting what is depicted as a criss-cross mesh structure. In column 12, line 17 onwards it states that the web 442 is in the form of a mesh material such as a bio compatible metal wire which can be woven by one or more lengths of an appropriate wire.

The Gabbay apparatus is for reinforcing a damaged or defective heart valve instead of for providing material for a valve flap, as in claim 1. It follows that the buttress of Gabbay would require different properties than the

valve flap of claim 1. In Gabbay, the prosthesis can be made of a material which tolerates a certain amount of deformation and then snaps back into shape. For the prosthesis of Gabbay to function as intended, it has to be firm in opposing the anterior mitral valve leaflet. If the prosthesis is not sufficiently rigid to do this, the pressure on the anterior mitral valve leaflet may push the structure aside, allowing central leaking and/or pro-lapse of the anterior leaflet into the left atrium. Thus, to function as intended, the prosthesis of Gabbay cannot be too flexible.

Applicant asserts that modifying Gabbay to use “knitted wire” instead of a mesh or weave would frustrate the intended purpose of Gabby since “knitted wire” is more flexible than woven wire, as stated on page 3, lines 15-23 of the present specification. As such, no motivation exists to modify Gabbay in the manner alleged in the Office Action. At least for such additional reason, Applicant asserts that claim 1 is patentable over the cited combination. Applicant asserts that the cited combination also fails to disclose or suggest the openwork structure being chainmail. Given the greater flexibility of knitted wire and chainmail, it follows that individual wire lengths in such structures may undergo less stress during bending in comparison to woven wire. In woven wire, the wire itself bends whereas, in knitted wire and chainmail, it is possible for the structure to give way and reorient to a certain extent without bending of wire lengths. Such a property provides an advantage to the one or more flaps of the claimed valve in extending their operational life.

Claims 2-7 and 9 depend from claim 1 and are patentable at least for such reason as well as for the additional limitations of such claims not disclosed or suggested.

Claim 10 sets forth a method that includes, among other features, providing a prosthetic valve in which a flap is made of a flexible openwork structure of a medically acceptable metal, wherein the flexible openwork structure is selected from the group consisting of: knitted wire and chain mail. As may be appreciated from the discussion above regarding the deficiencies of Silvestrini in view of Gabbay as applied to claim 1, the cited combination fails to disclose or suggest every limitation of claim 10. Claims 11 and 14 depend from claim 10 and are patentable at least for such reason as well as for the additional limitations of such claims not disclosed.

Claim 12 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Silvestrini and Gabbay in view of Yang (US Pub. No. 2002/0138138). Claim 12 depends from claim 11, the subject matter of which is discussed above. Yang does not remedy and is not alleged to remedy the deficiencies of the cited combination. Accordingly, claim 12 is patentable.

Also, at least page 5, lines 30-33 of the present specification define the "degradable" characteristic of the sealing material set forth in claim 12 and its advantages. The lubricious material described in paragraph 59 of Yang, especially the example of PTFE, fails to meet the definition in the present specification of a degradable sealing material. The Office Action does not provide evidence that it would "degrade" within the meaning of claim 12. Page 4 of the Office Action merely states it is known that PTFE "may be

formulated to be degradable.” Consequently, the rejection lacks support based on substantial evidence, as is required for a proper rejection, and should be withdrawn.


Under the Administrative Procedure Act (APA) applicable to the Office’s allegation of degradability, the standard of review applied to findings of fact is the “substantial evidence” standard. See, In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 2144.03 (2007). Essentially, the Office’s allegation appears to assume it is well-known that PTFE may be degradable. Applicant asserts this fact is not well known and traverses the allegation. It is not permissible for the Office to base rejections on unsupported assumptions.

Applicant herein adds new claims 15-20 supported at least by page 3, lines 15-23 and Figures 7a-d of the present specification. The Office Action does not allege that the cited references, considered alone or in combination, disclose the subject matter of new claims 15-20.

Applicant herein establishes adequate reasons supporting patentability of claims 1-7, 9-12, and 14-20 and requests allowance of all pending claims in the next Office Action.

Respectfully submitted,

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